

Abstract

The invention relates to a process for detecting or determining a C-peptide-containing impurity in a sample of recombinantly produced human insulin or a derivative thereof, by a non-radioactive assay, comprising the steps:

- (a) preparing a sample of recombinantly produced human insulin or a derivative thereof;
- (b) mixing the samples with dilution buffer;
- (c) adding a tracer to mixture (b);
- 10 (d) adding antibody specific for the C-peptide impurity to mixture (c);
- (e) adding "C-peptide second antibody bead" having at least one label to mixture (d); and
- (f) detecting or determining the presence of the C-peptide-containing impurity.

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